UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO: *The City of New York, et al.* *v.* *Abbott Laboratories, et al.*	Judge Patti B. Saris

PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS RELATED TO FEDERAL UPPER LIMITS ("FULs") AND APPLICABLE TO ALL THIRTEEN FUL DEFENDANTS (the "FUL THIRTEEN")

Pursuant to Rule 56.1 of the Local Rules of this Court, Plaintiffs, the City of New York and the New York Counties in MDL 1456 hereby submit this Statement of Undisputed Material Facts Related to Federal Upper Limits ("FULs") and Applicable to all FUL Thirteen Defendants whose published prices have been examined in connection with Plaintiffs' Motion for Partial Summary Judgment on Issues Related to the Federal Upper Limit and for Liability under New York Social Services Law 145-b (the "FUL Thirteen").[1] The subject drugs on this motion are: Albuterol .90 MCG Inhaler; Albuterol .83 mg/ml solution; Cefadroxil 500 MG Capsule; Clonazepam .5 MG Tablet; Enalapril

[1] The FUL Thirteen are: (1) Barr Laboratories, Inc.; (2) Dey, L.P./Dey, Inc.; (3) Ethex Corporation; (4) Ivax Corporation/Ivax Pharmaceuticals Inc.; (5) Mylan Laboratories, Inc./Mylan Pharmaceuticals, Inc./UDL Laboratories, Inc.; (6) Par Pharmaceuticals Companies, Inc.; Par Pharmaceutical, Inc.; (7) Purepac Pharmaceutical Co.; (8) Boehringer Ingelheim Roxane, Inc. f/k/a Roxane Laboratories, Inc.; (9) Sandoz, Inc.; (10) Teva Pharmaceuticals USA, Inc.; (11) Schering-Plough Corporation/ Schering Corp./Warrick Pharmaceuticals Corporation; (12) Watson Pharmaceuticals, Inc./Watson Pharma, Inc. and (13) Wyeth Pharmaceuticals, Inc.

Maleate 20 MG tablet; Isosorbide Mononitrate 60 mg Tablet; Lorazepam 1MG Tablet; Metropolol 100 MG Tablet; Ranitidine 150 MG Tablet (the "subject drugs").

Facts specific to each of the FUL Thirteen are set out in the individual Plaintiffs' Local Rule 56.1 Statements of Undisputed Material Facts filed together herewith.

The New York Medicaid Program

1. New York Medicaid, like all State Medicaid programs, is required to reimburse providers, at their "estimated acquisition cost" ("EAC") of the drug plus a reasonable dispensing fee. 42 C.F.R. 447.301 (2006).

2. EAC is defined as "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of the drug most frequently purchased by providers." *Id.*

3. The New York Medicaid reimbursement formula has always been set by the legislature. During the relevant period of 1997-2005 it provided that New York Medicaid would reimburse providers based on the FUL if a FUL was in place. Specifically:

> (b) for drugs dispensed by pharmacies:
>
> (i) if the drug dispensed is a multiple source prescription drug for which an upper limit has been set by the federal health care financing administration, [reimbursement will be] an amount equal to the specific upper limit set by such federal agency for the multiple source prescription drug,

N.Y. Soc. Serv. L. sec 367-a(9)(b)(i).

The Federal Upper Limit

4. The purposes of the Federal Upper Limit ("FUL") program are to ensure access to prescription drugs while achieving cost savings. Gaston, Sue (March 19, 2008) Vol. II 498:16-22 (Exhibit A hereto).

5. To achieve cost savings for states and Medicaid, CMS seeks to set a reasonable reimbursement rate on drugs that are commonly used by the Medicaid population in an outpatient setting. Gaston, Sue (January 24, 2008) 216:14-19; 245:12-246:16 (Exhibit B hereto); Gaston, Sue (March 19, 2008) Vol. II, 329:10-331:3; 456:10-457:6 (Exh. A hereto); see also Brief of the United States on the Federal Upper Limit, p. 2-3, *citing* 51 Fed. Reg. at 29563 (Docket No. 4413) (Exh. C hereto); Sexton, Gail (May 20, 2008) 72:21-76:11, 91:18-93:19 (Exh. D hereto).

6. A reasonable FUL was considered to be somewhere between WAC and AWP. Gaston, Sue, Vol. II (March 19, 2008) 446:1-453:1; 488:2-19. (Exh. A hereto).

7. Federal regulations provide that CMS may set a FUL when two criteria are met: (1) there must be at least three therapeutic equivalents (A-rated) listed for the generic drug in the FDA Orange Book publication, Approved Drug Products with Therapeutic Equivalence Evaluations; and (2) there must be at least three suppliers of the generic drug listed in the pricing compendia. 42 CFR § 447.332(a)(i) and (ii).

8. Once these two criteria were met, the regulations provided that CMS may establish the FUL by taking "150 percent of the lowest published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or if the drug is not commonly available in quantities of 100, the package size commonly listed)…" 42 CFR § 447.332(b).

9. At all times relevant hereto, CMS had a computer application ("FUL system" or "FULS") that analyzed the FDA Orange Book ratings and the publishing compendia (First Data Bank, Red Book and Medispan) price information to automatically

find the therapeutic equivalent with the lowest published price (AWP, WAC, and DP) and multiply it by 150 percent. Gaston, Sue (January 24, 2008) 232:22-237:9 (Exh. B hereto).

10. CMS's FULs program pulled published prices from First Data Bank, Red Book and Medispan to establish the FUL. Gaston, Sue (January 24, 2008) 145:5-146:16 (Exh. B hereto).

11. In addition to the two criteria mandated by the federal regulation governing the FUL, CMS on occasion engaged in a manual review to ensure availability of the drug and accuracy of pricing information. Gaston, (January 24, 2008) 257:3-12 (Exh. B hereto).

12. The 2003 Compliance Program Guidance for Pharmaceutical Manufacturers issued by the Office of the Inspector General of the U.S. Department of Health and Human Services, Federal Register, Vol. 68, No. 86, Monday May 5, 2003 ("2003 OIG Guidance"), provides:

> [Pharmaceutical manufacturers have a] legal duty to avoid submitting false or inaccurate pricing or rebate information to any federal health care program. 68 Fed. Reg. at 23732.
>
> The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent or misleading information is actionable. 68 Fed. Reg. 23733
>
> In sum, pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes. 68 Fed. Reg. 23734.

A copy of the 2003 OIG Guidance is attached as Exhibit E hereto.

Dated: May 15, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS RELATED TO FEDERAL UPPER LIMITS ("FULS") APPLICABLE TO ALL THIRTEEN FUL DEFENDANTS (THE "FUL THIRTEEN"), to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: May 15, 2009

/s/

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